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10/019,797

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Achim Gopferich

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|   |                                      |   |  |
|---|--------------------------------------|---|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | <b>Application No.</b><br>10/019,797 | <b>Applicant(s)</b><br>GOPFERICH ET AL. |  |
|   | <b>Examiner</b><br>ERIC E. SILVERMAN | <b>Art Unit</b><br>1618                 |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: none.  
 Claim(s) objected to: none.  
 Claim(s) rejected: 1-3, 5, 9, 10, 12-15, 33, 36-38, 41-44 and 67-74.  
 Claim(s) withdrawn from consideration: 11, 16-32, 65, 66 and 663.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

/Eric E Silverman/  
 Primary Examiner, Art Unit 1618

Continuation of 5. Applicant's reply has overcome the following rejection(s): the objection to the specification and the rejection under section 112, second paragraph.

Continuation of 11. does NOT place the application in condition for allowance because: (A) The rejection over Domb in view of Greenwald. Applicants first argue that the figure in the final rejection, purported to be representative of Domb, does not actually appear in Domb. While Applicants' are correct, this is not germane. Domb teaches the AB block copolymer poly(L-lactide-b-ethylene glycol). The figure that the examiner drew in the final action is the chemical structure of this polymer. The artisan of ordinary skill would immediately recognize that these structures are the unique chemical structures associated with the named compounds; the Examiner drew out the structure for the benefit of Applicants' representatives, who appear to be unfamiliar with chemistry, and to better explain the reasons for the rejection. Applicants then argue that Domb is not drawn to polymers that bind to drugs. This argument is not germane, because the elected species (see election mailed 12/17/08 and response entered 1/16/09) is drawn to a compound where the drug group d) is not bound to the polymer. As to the argument that Domb is not capable of forming a bond to a drug (component d), this also fails. Domb's polymers have hydroxyl and carboxylate end groups, which are capable of undergoing chemical reactions and forming chemical bonds to drugs. For example, the hydroxy group in the polymer could react with an acid group in a drug to form an ester bond. This is true even if Domb does not recognize or appreciate it. Applicants then argue that Greenwald does not cure the deficiency in Domb (Domb admittedly does not teach an amine terminated polymer) because Greenwald's polymers bind to drugs after reactions that require, among other things, 18 hours of reaction time followed by removal of solvent with vacuum. Applicants posit that this is not the "instant reaction" of the claims. This argument fails, because it contradicts Applicants' argument against the indefiniteness rejection that the term "instant reaction" has nothing to do with the duration of the reaction. As Applicants' correctly point out, the term "instant reaction," as it is used in this Application, is defined in the specification. The definition in the specification is quite broad, and the combination of Domb and Greenwald meet it.

(B) The rejection over Hirose in view of Greenwald. Applicants first allege that they have "previously argued that Hirose ... is not actually prior art against any of the current claims." Applicants cite Milburn and Wertheim to support this proposition. Applicants' reasoning is unclear; Milburn was decided in 1926, before the modern patent act containing section 102(e) was passed into law, and Wertheim does not discuss what is or is not prior art under 102(e). Even if neither of the cases was overruled (dispite Applicants' comments, the Examiner has never argued that they are not good law), neither address what is or is not prior art under 102(e). Applicants then argue that the rejection is flawed because Hirose teaches functionalization with NHS and similar activated esters, and does not teach whether the activated esters should be on the PLA or PEG portions of the polymers. Applicants note that the present invention is not drawn to polymers with activated esters, such as NHS, and instead requires an amine as the PEG terminus.